REMARKS

The Examiner contends that Applicants' amendment to the claims filed on 10/16/2002 does not comply with the requirements of 37 § C.F.R. 1.121(c) because the marked-up copy of claim 24 and the clean copy of claim 24 are different. Applicants note that no claim amendments were filed with the communication filed on 10/16/2002. Applicants assume that the examiner intended to refer to Applicants' response to restriction requirement and preliminary amendment filed July 29, 2002. The examiner asserts that in the response to restriction requirement and preliminary amendment filed July 29, 2002, there are a variety of symbols in the marked-up copy of the claims that are not found in the clean copy of the claims. Applicants respectfully disagree on the following grounds.

Applicants respectfully submit that the "symbols" correspond to marked-up versions of deleted matter (specifically, colons and semi-colons) using strikethrough. As per 37 C.F.R. 1.121(c), "...the changes may be shown by brackets (for deleted matter), **or by any equivalent marking system**." (emphasis added). In the response filed July 29, 2002, Applicants used the well-known and widely accepted marking system as provided in the most recent versions of Microsoft WORD™. In this marking system, deleted matter is shown by strikethrough (*e.g.* ~~strikethrough~~), while inserted matter is underlined (*e.g.* underlined). Therefore, the deleted colon and semicolon of original claim 24, when deleted appear as follows: ~~:~~ and ~~;~~. The marked-up version of claims 24 using this system is shown below.

24. (Amended) A method for stimulating and/or expanding T cells in a mammal, comprising administering to a mammal a ~~pharmaceutical~~ composition comprising~~:~~,

~~(a) one or more of:~~

~~(i)~~ a WT1 polypeptide comprising the polypeptide set forth in SEQ ID NO:2~~;~~

~~(ii) a polynucleotide encoding a WT1 polypeptide; or~~

~~(iii) an antigen presenting cell that expresses a WT1 polypeptide;~~ and

~~(b)~~ a physiologically acceptable carrier or excipient~~.~~

~~and~~ thereby stimulating and/or expanding T cells in a mammal.

When copied and "accepting all changes" using the appropriate function in the Microsoft WORD™ program, the amended, clean copy of the claim appears as follows:

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24. (Amended) A method for stimulating and/or expanding T cells in a mammal, comprising administering to a mammal a composition comprising, a WT1 polypeptide comprising the polypeptide set forth in SEQ ID NO:2 and a physiologically acceptable carrier or excipient, thereby stimulating and/or expanding T cells in a mammal.

Applicants respectfully submit that the marked-up copy of the amended copy contains no extra symbols as compared to the clean copy of the amended claim.

Nevertheless, for the convenience of the Examiner, attached is a new "VERSION WITH MARKINGS TO SHOW CHANGES MADE" showing the same amendments made in Applicants' response filed July 29, 2002, along with a new clean copy of the amended claims.

Following are the amended claims 16-18 and 24 as filed in Applicants' response filed July 29, 2002:

16. (Amended) A method for enhancing or inducing an immune response in a human patient, comprising administering to a patient a composition comprising:

(a) a WT1 polypeptide that comprises an immunogenic portion of a native WT1 or a variant thereof that differs in one or more substitutions, deletions, additions and/or insertions such that the ability of the variant to react with antigen-specific antibodies and/or T cell lines or clones is not substantially diminished, wherein the polypeptide comprises the polypeptide set forth in SEQ ID NO:2; and

(b) a physiologically acceptable carrier or excipient;

and thereby enhancing or inducing an immune response specific for WT1 or a cell expressing WT1 in the human patient.

17. (Amended) A method for enhancing or inducing an immune response in a patient, comprising administering to a patient the composition according to claim 1.

18. (Amended) A method for enhancing or inducing an immune response in a human patient, comprising administering to a patient an immunogenic composition comprising:

(a) a WT1 polypeptide that comprises an immunogenic portion of a native WT1 or a variant thereof that differs in one or more substitutions, deletions, additions and/or insertions such that the ability of the variant to react with antigen-specific antibodies and/or T cell lines or clones is not substantially diminished, wherein the polypeptide comprises the polypeptide set forth in SEQ ID NO:2; and

(b) a non-specific immune response enhancer;

and thereby enhancing or inducing an immune response specific for WT1 or a cell expressing WT1 in the human patient.

24. (Amended) A method for stimulating and/or expanding T cells in a mammal, comprising administering to a mammal a composition comprising a WT1 polypeptide comprising the polypeptide set forth in SEQ ID NO:2 and a physiologically acceptable carrier or excipient, thereby stimulating and/or expanding T cells in a mammal.

Following this communication and the amendment filed July 29, 2002, claims 16-18, 24, and 47-55 are under examination. Favorable consideration of the present application in view of the above Remarks is respectfully requested.

Respectfully submitted,
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Non-elected claims 1-15, 19-23, and 25-46 have been cancelled.

New claims 47-55 have been added.

Claims 16-18 and 24 have been amended as follows:

16. (Amended) A method for enhancing or inducing an immune response in a human patient, comprising administering to a patient a[pharmaceutical] composition comprising:

(a) a WT1 polypeptide that comprises an immunogenic portion of a native WT1 or a variant thereof that differs in one or more substitutions, deletions, additions and/or insertions such that the ability of the variant to react with antigen-specific antibodies and/or T cell lines or clones is not substantially diminished, wherein the polypeptide comprises the polypeptide set forth in SEQ ID NO:2; and

(b) a physiologically acceptable carrier or excipient;

and thereby enhancing or inducing an immune response specific for WT1 or a cell expressing WT1 in the human patient.

17. (Amended) A method for enhancing or inducing an immune response in a patient, comprising administering to a patient [a pharmaceutical]the composition according to [any one of]claim[s 12-15] 1.

18. (Amended) A method for enhancing or inducing an immune response in a human patient, comprising administering to a patient [a vaccine]an immunogenic composition comprising:

(a) a WT1 polypeptide that comprises an immunogenic portion of a native WT1 or a variant thereof that differs in one or more substitutions, deletions, additions and/or insertions such that the ability of the variant to react with antigen-specific antibodies and/or T

cell lines or clones is not substantially diminished, wherein the polypeptide comprises the polypeptide set forth in SEQ ID NO:2; and

(b) a non-specific immune response enhancer;

and thereby enhancing or inducing an immune response specific for WT1 or a cell expressing WT1 in the human patient.

24. (Amended) A method for stimulating and/or expanding T cells in a mammal, comprising administering to a mammal a [pharmaceutical]composition comprising[:],[

(a) one or more of:

(i)]a WT1 polypeptide comprising the polypeptide set forth in SEQ ID NO:2[;

(ii) a polynucleotide encoding a WT1 polypeptide; or

(iii) an antigen-presenting cell that expresses a WT1 polypeptide;] and [

(b)]a physiologically acceptable carrier or excipient,[;

and] thereby stimulating and/or expanding T cells in a mammal.

Application No.: 09/685830

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other: _____

Applicant Must Provide:

☐ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☐ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

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